

REMARKS

By the above actions, claim 22 has been added. In view of these actions and the following remarks, reconsideration of this application is now requested.

The rejection of claims 1-7, 19 and 21 under 35 U.S.C. § 102, as being anticipated by U.S. Patent 6,325,755 to *Bushek et al.*, is inappropriate, because *Bushek et al.* fails to disclose all of the features recited in the claims. For example, independent claim 1 recites:

a micromanipulator for positioning the transducer and for fixing the transducer in a position set by the micromanipulator, the micromanipulator being adapted to be fixedly attached by fixing means to a cranial vault; and
a releasable coupling unit disposed between the transducer and the micromanipulator, said coupling unit, in an assembled state, fixing the transducer with respect to the micromanipulator, and, in a released state, permitting removal of the transducer from the micromanipulator.

The present invention recognizes and addresses problems discovered by Applicants with respect to conventional devices, such as that of *Bushek et al.* (corresponding PCT application WO 00/48426). Specifically, the Specification at pages 7-8, paragraph [00016], states (emphasis added) that:

In a hearing system known from International Patent Application Publication WO 00/48426 a unit consisting of an actoric electromechanical transducer and of a positioning and fixation system (here called "micromanipulator") is detachably connected to mounting means fixedly attached to the skull, so that in case of need the micromanipulator together with the transducer may be exchanged without disassembly of the mounting means being required. In fact, the removal of the mounting means may require a relatively invasive intervention because the operative access to the fixing screws of the micromanipulator must be exposed. Furthermore it may happen that the respective screw holes in the cranial vault can not be reused because the screws normally are self-cutting and the respective holes in the bone are widened during unscrewing and no longer can provide for an absolutely secure seat of new screws. It may also happen that the "old" access path to the point of aim of the transducer coupling element can be used no longer or only in a very restricted manner. However, the prior solution still leaves much to be desired. Thus, **after an**

exchange of the micromanipulator/transducer unit this unit must be newly adjusted in a troublesome manner in order to exactly align the transducer with the aimed site of stimulation. Thereby the reversion operation becomes distinctly more risky and prolonged, particularly when the transducer postoperatively became defect and therefore an exchange of the transducer is required. In addition it may happen that the intervention, which otherwise possibly could take place under local anesthesia, must be carried out under total anesthesia because the depth and duration of the operation make this necessary. The fixed interconnection between transducer and micromanipulator furthermore involves the technical drawback that it becomes extremely difficult to find a design for both components which avoids left-hand/right-hand differences of the system. This leads to the economical disadvantage that for each new implantation two complete transducer-micromanipulator systems must be delivered because it may be that only shortly before the operation the decision is made together with the patient which side will be operated. **Another economical disadvantage is that a reversion operation because of a defect of the transducer requires explantation and throwing away of a fully functioning micromanipulator because the existing laws prohibit a reuse thereof.** An other important drawback is that, with the further developments of the electromechanical transducers to be expected, such improved products again can be offered to a patient already wearing an implant merely in the form of a **complete exchange of a system involving both the transducer and the micromanipulator.**

Accordingly, as recognized by Applicants and as would be recognized by those of ordinary skill in the art, the micromanipulator of *Bushek et al.* includes all of the components shown in FIG. 3 of *Bushek et al.*, except for the transducer 162 and the support assembly 10. Therefore, the support assembly 10 of *Bushek et al.* would correspond to the claimed "fixing means" recited in independent claim 1, as the support assembly 10 is adapted for attaching the micromanipulator of *Bushek et al.* to a cranial vault (col. 11, lines 28-31). Thus, *Bushek et al.* fails to disclose "a releasable coupling unit disposed between the transducer and the micromanipulator," as recited in independent claim 1, because the transducer assembly of *Bushek et al.* only includes the micromanipulator, the transducer 162, and the support assembly 10.

Accordingly, the interpretation of *Bushek et al.* in the present Office Action is believed to be unreasonable. Specifically, the present Office Action, at page 3, takes the unreasonable position that the mounting flange 145 of the support assembly 10 of *Bushek et al.* corresponds to the claimed micromanipulator. However, as noted above, the support assembly 10 of *Bushek et al.* would correspond to the claimed "fixing means," as the exact positioning of the transducer 162 of *Bushek et al.* is done by adjusting the transducer assembly 168 relative to the sleeve 135, which is attached to the support assembly 10. Thus, *Bushek et al.* fails to disclose "a releasable coupling unit disposed between the transducer and the micromanipulator," as recited in independent claim 1.

By contrast, independent claim 1 is directed to a micromanipulator 18 arranged for releasable attachment of a coupling element 22 having a transducer 12 disposed therein. Advantageously, the invention of independent claim 1 has numerous advantages over the transducer assembly of *Bushek et al.*, for example, as disclosed in the Specification, pages 8-9, paragraph [00018], which states:

On occurrence of a postoperative transducer defect the releasable coupling unit provided for in conformity with **the invention permits an exchange of the transducer alone, that is without exchanging the micromanipulator, too.** The same is true when an exchange of the transducer becomes desirable for other reasons, for example **when improved transducers become available** due to further developments of the transducer technology. **The transducer position adjusted by the micromanipulator is preserved even in case of an exchange of the transducer, so that a new adjustment of the micromanipulator does not become necessary.** In view of the fact that the transducer alone may be exchanged, **the above discussed problems with respect to left-hand/right-hand differences also do not occur.** (Emphasis added.)

Accordingly, the micromanipulator 18 includes all that is necessary to effect positioning of the transducer 12, rather than reliance on further releasable components, as is the case with *Bushek et al.* In addition, the transducer assembly of *Bushek et al.* suffers from all the problems recognized and addressed by the invention recited in independent claim 1, and as noted above.

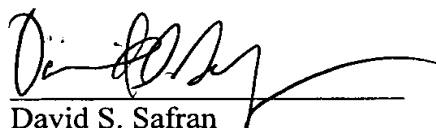
U.S. Patent 5,935,170 to *Hakansson et al.* was not relied on for the noted features recited in independent claim 1 and properly so. Nonetheless *Hakansson et al.* fails to cure the noted deficiencies in *Bushek et al.*

New claim 22 has been added. Claim 22 is allowable over *Bushek et al.* and *Hakansson et al.*, for at least the reasons stated above, and additionally because these references fail to disclose, teach or suggest the feature "wherein said coupling unit, in the released state, permitting removal of the transducer from the micromanipulator while maintaining the set position," as recited in claim 22, and supported by the specification at pages 8-9, paragraph [00018].

The prior art that has been cited, but not applied by the Examiner, has been taken into consideration during formulation of this response. However, since this art was not considered by the Examiner to be of sufficient relevance to apply against any of the claims, no detailed comments thereon is believed to be warranted at this time.

While the present application is now believed to be in condition for allowance, should the Examiner find some issue to remain unresolved or should any new issues arise, which could be eliminated through discussions with Applicants' representative, then the Examiner is invited to contact the undersigned by telephone in order that the further prosecution of this application can thereby be expedited.

Respectfully submitted,



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